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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,781	02/11/2004	Thomas P. Clement	6034-74031	5114
23643	7590	10/23/2006		
BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204				
			EXAMINER TOY, ALEX B	
			ART UNIT 3739	PAPER NUMBER

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/776,781	<b>Applicant(s)</b> CLEMENT ET AL.	
	<b>Examiner</b> Alex B. Toy	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 16, 18-21 and 41-49 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 and 41-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/21/04; 3/18/05; 9/15/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Invention II (claims 16-21) and Species I (Figs. 1-3a) in the reply filed on September 15, 2006 is acknowledged. In accordance with this election, applicant has voluntarily canceled claims 1-15, 17, and 22-40 and withdrawn claims 18-21. New claims 41-49 depend from examined independent claim 16. In summary, claims 1-15 and 17-40 are canceled or withdrawn. Claims 16 and 41-49 are examined.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16 and 41-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adair (U.S. Pat. 4,269,174) in view of Khan (U.S. Pat. No. 5,824,359).

Regarding claim 16, Adair discloses an electro-cautery probe 16 for attachment to and use with a cauterization device to cut and/or cauterize tissue of a patient in surgery, the electro-cautery probe having at least a surface 26 of the electro-cautery probe which contacts a patient's tissue to be cut and/or cauterized (col. 4, ln. 1 – col. 5, ln. 19 and Figs. 1-11).

The claim differs from Adair in calling for the surface of the electro-cautery probe to be coated with a coating comprising an amphiphilic lipid. Khan, however, teaches coating a needle with an amphiphilic lipid (lecithin) as a lubricant to facilitate its insertion into the patient (col. 2, ln. 5-14, 49 and col. 3, ln. 16-33). The needle of Khan is analogous to the electro-cautery probe surface 26 of Adair because both are needles that puncture skin and deliver fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the electro-cautery probe surface (needle) 26 of Adair with an amphiphilic lipid in view of the teaching of Khan in order to provide a lubricant to facilitate its insertion into the patient.

Regarding claims 41-44, Khan discloses that the coating comprises lecithin, which is inherently: an amphiphilic phospholipid, a glycerol-based lipid, and a glycerol-based phospholipid.

Regarding claims 45 and 48, it is well-known that soy is a main source of lecithin and that soy can cause an allergic reaction. Furthermore, since applicant discloses using a commercially available source of non-allergenic soy lecithin (pg. 6, ln. 19-24), it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to have used such a commercially available source of lecithin in the device of Adair in view of Khan in order to prevent allergic reactions in patients.

Regarding claims 46 and 47, applicant does not disclose any criticality or unexpected result associated with using a lecithin with either of the claimed viscosities. Furthermore applicant discloses that lecithin with differing viscosities and other varying properties are all within the scope of the invention (pg. 7, ln. 19-27). Therefore, it would have been obvious and required only routine skill in the art at the time the invention was made to have used a lecithin with a viscosity of 8090 or 12000.

Regarding claim 49, applicant recites a very broad chemical formula for lecithin without any criticality or unexpected result. Since Khan discloses using lecithin with a chemical formula that is in accordance with claim 49 (col. 3, ln. 23-33), claim 49 is unpatentable of Adair in view of Khan.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4744992 A	USPAT	Mitchell; Cheryl R. et al.
US 5498421 A	USPAT	Grinstaff; Mark W. et al.
US 5643580 A	USPAT	Subramaniam; Raj

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*  
10/16/06

*Michael P. Pfeley*  
MICHAEL PEFLEY  
PRIMARY EXAMINER  
AU 3739